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Re-evaluation Note REV2016-01

Special Review Decision: Quintozene

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Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing quintozene based on decisions taken by the European Commission in 2000 and by Switzerland in 1998. The PMRA evaluated the aspects of concern that prompted the special review in accordance with the subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2014-07, *Special Review of Quintozene: Proposed Decision for Consultation* and it outlines the Agency's proposed decision and the reasons for it.

Comments received during the consultation process were taken into consideration in making this special review decision, and they did not result in changes to the proposed regulatory decision as described in REV2014-07. Therefore, the PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of technical grade active ingredient products containing quintozene in Canada.

Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments. Please refer to REV2014-07 for more information on the PMRA's special review of quintozene. Regulatory Directive DIR2014-01, *Approach to Special Reviews,* presents the details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection[1] regarding this decision on quintozene within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[1] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2014-07, *Special Review of Quintozene: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to this special review and provides responses below.

1.0 Scope of the special review of quintozene

1.1 Comment on the information considered by the PMRA for the special review

A special review should give thorough consideration to the concerns leading to a ban on the active ingredient in another country to assess whether the risks and value of the pest control product are acceptable for continued registration in Canada. This could include obtaining and analyzing relevant data and examining the PMRA's approach to risk assessment in light of alternatives (in other words, the approach in the country with a ban). A special review may also provide an opportunity to consider new information or emerging issues related to health and environmental risks of the subject pest control product that may not have been available to or considered previously by PMRA or the country with a ban in place.

PMRA Response

When a special review is initiated under subsection 17(2) of the *Pest Control Products Act*, the PMRA carries out an analysis of the available information from the Organisation for Economic Co-operation and Development (OECD) member countries (where the pesticide is prohibited) to identify the aspect(s) of concern related to the prohibition. For quintozene, the PMRA reviewed the available information from the European Union and Switzerland, and the aspects of concern that prompted the special review were identified as occupational and dietary exposure, persistence in the environment, bioaccumulation, effects on earthworms and toxicity to aquatic organisms. The aspects of concern were then evaluated as required under subsection 18(4) of the *Pest Control Products Act* based on the available relevant information including information from the European Union and Switzerland.

Please note that as outlined in the Regulatory Directive DIR2014-01, *Approach to Special Reviews*, the PMRA requested information related to the aspects of concern of quintozene products from other federal/provincial government departments and agencies. No information related to the aspects of concern was received.

Currently, no end-use products containing quintozene are registered in Canada. There are only two technical grade active ingredients registered in Canada and they are used only for the manufacturing or formulation of end-use products. These quintozene technical products are not currently used because of the discontinuation of end-use products. Consequently, occupational and environmental exposure from the use of these technical products is not expected.

The PMRA has assessed dietary exposure from all food uses, including imported foods, and determined that dietary exposure is not of concern. On this basis, the PMRA concluded that pest control products containing quintozene do not pose unacceptable risks to human health or the environment under the current registration status.

1.2 Comment on review of currently registered products

The PMRA has not evaluated available scientific information related to the aspects of concern, a requirement for special review. Instead, REV2014-07 suggests that special review is unnecessary at this time because end-use products containing quintozene are discontinued. However, the PMRA is proposing to continue these registrations on the basis that the two remaining quintozene products are not currently in use and therefore do not pose an exposure hazard. This is a perversion of risk assessment logic. If the use of products containing quintozene may pose unacceptable risks, registration of these products and the active ingredient should be canceiled, regardless of whether the pesticide is currently in use or not.

PMRA Response

The PMRA employs a scientifically based risk assessment approach (human health and environment) instead of a hazard-based assessment approach for the regulation of pesticides and, considers both hazard (effects) and exposure levels of pesticides. Risk estimation compares toxicity and the amount of pesticide an individual or a given organism may be potentially exposed to (in other words, the numerical relationship between exposure and effects). In the case of quintozene, as there are no end-use products currently registered in Canada and the technical products are not being used, there is no potential exposure to humans or the environment. Therefore, the PMRA concluded that the potential risk to human health and the environment from the technical products is not expected to be of concern.

1.3 Comments on the registration of new products containing quintozene

The *Pest Control Products Act* does not require public consultation on decisions to register new products if the active ingredient is already registered. Punting evaluation of the aspects of concern to a potential future product registration decision amounts to an end-run around the consultation requirements for a special review.

PMRA Response

Pest control products that do not pose unacceptable risks to human health and the environment are approved under the *Pest Control Products Act*. For quintozene, any future application that seeks registration of uses that were cancelled through re-evaluation will proceed as a major new use. As such, the PMRA would then conduct a thorough scientific assessment of the health and environmental risks and value of those pest control products, and, as required by the *Pest Control Products Act*, a proposed decision document would be published for public consultation before making a final decision.

2.0 Special review process

2.1 Comments on initiating special reviews

The PMRA should develop a systematic approach to initiate a special review when a member country of the OECD prohibits all uses of an active ingredient for health or environmental reasons. It was noted that quintozene has been prohibited in Switzerland since 1998 and in the European Union since 2000, but the PMRA did not initiate the legally required special review until 30 December 2013.

PMRA Response

The PMRA continues to monitor the regulatory status in OECD member countries of products containing active ingredients registered in Canada. The PMRA seeks information through participation in international working group meetings such as the OECD and the Rotterdam Convention, as well as from the publicly available information.